B.8 Quality

(Approved by CMS August 2010)

Quality management is a critical operational feature that an organization employs to continually determine whether it operates in accordance with the approved design of its program, meets statutory and regulatory assurances and requirements, achieves desired outcomes, and identifies opportunities for improvement. Quality management is a system of accountability used in health care, designed to allow oversight and evaluation of provision of services to persons not directly involved in the program administration. This allows a non-biased interpretation of evaluation findings.

Overall QMS

The purpose of establishing a quality management strategy (QMS) is to ensure provision of effective and quality services in order to maintain the health and welfare of demonstration participants. CMS requires the state to provide assurances that six QMS areas are in place for demonstration participants:

1. Determination of level of care/need for skilled care
2. Description of service plan
3. Identification of qualified HCBS providers
4. Assurance of health and welfare
5. Administrative authority
6. Financial accountability

Collectively, these areas provide checks and balances to ensure that demonstration participants receive safe, competent care to support good health and well being. Besides collecting data on all of these areas, an annual case record review is also performed. Specific QMS information for each waiver, program and/or state plan service is listed under its specific area at the end of this section.

QMS on State Level

The DHCS Long-Term Care Division's (LTCD) QMS is to develop and implement discovery tools and methods to evaluate LTCD's effectiveness in compliance with the waiver assurances and policies and procedures. As a result of discovery activities, LTCD will develop, implement, and evaluate remediation actions to enhance, correct, and/or improve LTCD's compliance. The LTCD Quality Assurance (QA) Unit is responsible for developing discovery activities, collecting, and analyzing the data from the discovery activities. The QA Unit utilizes the following tools for discovery: Internet-based Case Management Information Systems (CMIS); Case Record Review; Provider Visit Review; Event/Issue database; CA-MMIS; and California Department of Developmental Services' Case Management Information Payrolling System (CMIPS).

The QA Unit and the DHCS LTCD's Medical Consultant, a licensed physician, are responsible for conducting the Annual Case Record Reviews on active NF/AH waiver

cases. The selected sample size for the number of case records to be reviewed is determined by using the Sample Size Calculator located at http://www.surveysystem.com/sscalc.htm.

Annual Case Record Review

The annual Case Record Review looks for evidence that the DHCS LTCD nurse evaluators have documented their observations of any issues concerning the participant's health care needs. These needs include: medication management and appropriate use, and that file notes confirm the safeguards are in place to protect the participant from life endangering situations or conditions of abuse, neglect and/or exploitation.

Currently, an annual case record review is conducted by the LTCD's QA Unit staff using a Record Review Tool to document evidence of compliance found in the case record and the provider visit report. The LTCD nurse evaluators evaluate all participants' health and safety. The information discovered prompts an interview with the participant, legal representative/legally responsible adult(s) and/or circle of support persons, about any occurrence of unscheduled hospitalizations, emergency room visits, issues with medications, and/or any situation that could endanger the participant. Documentation of the event outcomes is recorded.

The annual report identifies risk factors and monitors the completion of an Event/Issue Report submitted to the QA Unit when issues concerning health and safety are identified in the case record or Provider Visit Report. This identification is necessary so modifications can be offered to promote participant independence and safety. The QA Unit works with a DHCS contractor for analysis of cost reports. Cost reports are analyzed by for trends and patterns across waiver populations.

Quality Improvement

The QA Unit utilizes the following data sources for issue analysis and discovering potential improvements in waiver administration:

- Internet-based Case Management Information Systems (CMIS)
- Case Record Review Sampling
- Provider Visit Review
- Event reports and database
- California Medicaid Management Information System (CA-MMIS)
- California Department of Social Services' Case Management Information Payroll System (CMIPS)
- NOA and outcomes
- Evidence and accuracy of LOC assessments

Analysis of these data reveal trends and patterns of service utilization and consumer outcomes that sometimes are the basis for changes to policy, procedures, and

allocation of resources. This information will be used for future outreach activities and identification of best practices.

Due to delayed implementation of the demonstration, participants could not be included in a Participant Satisfaction Survey conducted in early 2008 with specific NF/AH waiver enrollees between the ages of 18 and 64 . The survey was designed to determine the need and potential to improve access to HCBS services and to identify unmet needs. Approximately 200 waiver enrollees voluntarily provided anonymous feedback directly to DHCS. The survey revealed enrollees' favorable satisfaction with services and service providers. Demonstration participants who choose to enroll in this waiver will be afforded the opportunity to participate in the next survey, the date of which has not been set.

Potential Conflict of Interest

Another level of quality management which occurs at the state level is the prevention of a potential conflict of interest with organizations contracting with the CCT. As a measure of prevention, the CCT project team worked with the DHCS Office of Legal Services (OLS) to develop zero-dollar contracts for lead organizations. The project director will consult OLS, as needed, if conflicts of interest are suspected. If a conflict of interest should arise, the project director will follow the DHCS policy to investigate and remedy the situation as soon as possible.

QMS for MFP Demonstration

Quality management is an integral part of California Community Transitions. Besides performing routine fiscal and service oversight, the demonstration provides the opportunity for the project nurse, lead organizations, and transition team members, to monitor participants' health and safety, particularly when critical events occur.

The CCT project team is responsible for the oversight of event/issue reporting for demonstration participants. Rather than create a new program the project team will:

1. Use Appendix G: Participation Safeguards of HCBS Waiver Application Version 3.4 - the DDS Reporting Requirements, dated 03/26/2008 as a baseline and work within the requirements of each waiver/program and/or state plan service utilized by their participants.
2. Work closely with the DHCS QA Unit and/or other program staff, in both monitoring oversight of event occurrence reporting, incident evaluation, investigation, follow-up, and file auditing.
3. Work with the California Department of Public Health's Licensing & Certification program and other state agencies as required by regulation and law

CMS has notified MFP grantees that the monitoring component of Critical Incident Reporting and Management System, overseeing the health, safety, and welfare of participants, must be in place by month six after approval. The project team will work

with DHCS' Home and Community-Based Services Critical Event System, which has been designed, in conjunction with Licensing and Certification, to report event occurrences experienced by waiver beneficiaries. The system currently utilizes an Event Issue Report to "collect data in a pro-active, non-punitive manner on events and issues affecting the health and safety of Medi-Cal beneficiaries who are involved in a program administered by the Long-Term Care Division."[1]

In early June 2008, LTCD management convened a Critical Incident Work Group to standardize the Event Occurrence Form and streamline the reporting process within the Division. Utilizing the current information from the recent MFP Quality Management teleconference, and the new waiver language for the DD Waiver, this work group will work to standardize procedures among the various waivers and programs to conform to CMS requirements. The work group, which includes the CCT project nurse, will meet bi-weekly with the goal of standardizing across waivers and programs. The project research analyst currently is developing a database to capture the information required for event occurrence oversight.

QMS Monitoring

A variety of health and safety issues can occur when health care services are involved. While any and all event issue reports filed will be documented, reviewed, and a remediation plan devised (as needed), the main focus of these event occurrences will be in the following areas:

- Elder or dependent adult abuse
- Medication monitoring
- Health and safety issues (equipment malfunction, visits to emergency department, and/or hospital admission, etc.)

The state assures that at minimum, standards outlined in Appendix H of the NF/AH waiver will govern the quality component of CCT. The LTCD QA Unit will be kept apprised as each new demonstration participant is enrolled so that they can include all demonstration participants in the QMS. The same level of quality assurance and improvement activities will govern a participant's transition and the first year of community living. Standards and procedures for clinical eligibility assessments and service planning have previously been approved under each specific HCBS waiver and/or state plan service.

Any event occurrence that is reported will be documented by a provider and/or participants' support systems, and reviewed by the project nurse and transition coordinator, as well as the QA Unit, per the quality management procedure. Project staff will retain a log of all event occurrences, as will the QA Unit, but the primary tracking will be related to equipment failure, emergency room visits and hospital admissions.

[1] Per HCBS Program Letter 2008 – 02, p1, Event Issue Report

California Community Transitions Event Occurrence System

The DHCS LTCD has a event occurrence system in place. Using that same structure, the project team has developed its own system which it will operate in conjunction with the LTCD's system. The system will begin on the first day participants are at home and continue for the duration of the demonstration. In addition, the same system will be in place after the demonstration year ends, when the participant's services continue under the waiver.

Definition of a Critical Event

A critical event is any incident posing an imminent danger to a participant's health, safety, or welfare. But not all critical events regarding health and safety will fall into the category of suspected abuse. Even so, their occurrence signifies the need for immediate action on the part of a provider or personal attendant.

The terms "serious reportable event" and "reportable event" are used for documenting two categories of critical events. All reportable events, whether falling under the serious reportable event category or the reportable event category, must be submitted on the CCT Event/Incident Report Form by following the CCT Event/Issue Report Procedure.

Serious Reportable Event

A serious reportable event is defined as an event that involves a life threatening situation or where there is an imminent threat to the health, safety, and welfare of the demonstration participant. Examples of serious reportable events are:

- Participant abandonment
- Abuse and/or neglect, by self or another person, physically, sexually, emotionally or psychologically (potential or actual)
- Death
- Occurrence of a medical emergency
- Participant becomes lost or wanders away from home

Whenever a serious reportable event occurs, a participant's health and safety is of first concern. Once that is ensured, verbal notification of the event must be initiated, followed by completion of a written Event/Issue Report Form and sent to the CCT project director, and documented in the participant's file.

Reportable Event

A reportable event is defined as an event that may affect the health, safety, and welfare of participants, but does not immediately jeopardize their health, safety, or welfare. Examples of reportable events are:

- Financial abuse
- A care attendant who has not shown up
- Broken or failed equipment

- Participant becomes injured in any way
- Participant is involved in any type of law enforcement activity or code violation
- Medication problems or other medication issues occur
- Restraining of a participant

State Oversight of Critical Events

The DHCS Long-Term Care Division's QA Unit is responsible for the oversight of event/issue reporting and the State's response to critical events affecting HCBS waiver enrollees. Critical event documentation is maintained electronically for use in quality assurance monitoring. The QA Unit tracks critical events and the actions that led to resolving the issues. The QA Unit monitors follow-up actions to determine:

- If the events were documented accurately.
- If actions have been taken to ensure the participant's health and safety.
- What was the ultimate outcome?
- Whether there are systemic service delivery issues that require remediation.

Findings from reports on critical events are compiled in an annual report by the QA Unit. The annual report is used to develop an action plan for quality improvement. In addition, current annual audits are performed on random files for quality monitoring.

CCT –Event Occurrence Reporting Procedure

The Quality Assurance System for the CCT encompasses the following steps:

1. Reporting and documentation of the event
2. Submission of follow-up information
3. Assessment and investigation of incident
4. Development of a remediation plan
5. Evaluation of steps taken to prevent recurrence of the situation.

Reporting and Documentation of Event

Reporting and documentation are key parts of any quality management system. If incidents are not reported, and then documented in hard copy form (writing and/or electronic format), there is not enough information for processing to be done. State CCT project staff will work with lead organizations, transition coordinators, and service coordinators to provide education and training to ensure that all serious reportable events and reportable events affecting health, safety and welfare of demonstration participants are reported and documented.

Reporting a serious reportable and/or reportable event is the responsibility of all service providers of demonstration participants. CCT staff members are responsible for completion of an Event/Issue Report when they either discover or receive information of

an event or issue that affects or can affect the health and safety of a participant. (CCT staff includes members of lead organizations, regional transition teams, and others who contract with DHCS to work on the demonstration.) In the case of a parent or participant who is a designated provider, that person is exempt from these reporting requirements.

Reporting and documenting an event takes two forms in most situations: telephone reporting and follow-up written documentation, usually completion of a required form. In some cases more than one form may need a state required form and the CCT required form. Except for the state-mandated reports of suspected child, dependent adult or elder abuse, state staff and service providers will adhere to the HIPAA of 1996 to ensure all demonstration participants' PHI is protected.

Documentation will include:

- Date the event/issue was discovered or reported;
- Date the event/issue occurred;
- Type of event/issues (i.e. staffing, medication, equipment, abuse, neglect, exploitation);
- What was done about the situation
- To whom situation was reported
- All other information requested by law, statute, and department policy.

The waiver case manager/service coordinator must provide the following information:

- Description of the event (the who, what, when, where, and how)
- Contacts to the primary care physician, family and service providers, if applicable
- Follow-up actions
- Reports to the Department of Public Health, Licensing & Certification Program for events involving specific facility or provider types: nursing facilities, intermediate care facilities, home health agencies, adult day health care centers, pediatric day health care, congregate living health facilities, and certified home health aides.
- Reports to the Department of Social Services, Community Care Licensing Division for events involving residential care facilities for the elderly, adult residential care facilities, adult day care and child care facilities

Except for the state-mandated reports of suspected child or dependent adult or elder abuse, state staff and service providers will adhere to the HIPAA of 1996 to ensure all demonstration participants' PHI is protected.

Notification Timeline	
If a CCT participant experiences a:	Then:
Serious reportable event	**Child Protective Services (CPS) Reporting** requirements: (mandatory) VERBAL: Telephone report to CPS immediately or as soon as practically possible. WRITTEN: Written information completed within 36 hours of receiving information. **Dependent Adult and Elder Abuse Reporting** requirements: (mandatory) VERBAL: Telephone report to Adult Protective Services immediately or as soon as practically possible. WRITTEN: Written information completed within two working days of receiving following occurrence of event. **All other occurrences**: Unless otherwise directed the following schedule will be used for all serious reportable events: 1. Service provider or personal attendant immediately verbally notifies lead organization of incident, or as soon as practically possible. A follow-up written report will be completed and submitted within 48 hours of event occurrence. 2. Lead organization submits a written Event/Issue Report of incident to project director within 24 hours. 3. Lead organization reviews and modifies the written Event/Issue Report and provides additional written information if necessary, e.g., other persons involved at the time of incident, results of action taken.
Reportable event	Unless otherwise directed the following schedule will be used for all reportable events: Written report to the CCT project director within 5 days.

Submission of Follow-Up Information

If new information is learned by a CCT provider or staff member regarding an event which has occurred, s/he is required to file an updated follow-up report with the new information to the CCT project nurse within three days of learning of the information. This information may include change in participant's status, services, etc.

Assessment and Investigation of Incident

Once a serious reportable event and/or reportable event report has been received, the following process will be followed by CCT staff, in conjunction with the LTCD's QA Unit. The transition coordinator will consult with the demonstration participant and service/case manager about actions needed to be taken to prevent/correct the event that occurred, and report information to the project nurse. Then the project nurse and the QA Unit will review all reported event occurrences involving demonstration participants. The data will be analyzed and monitored for ongoing concerns of affected participants. DHCS will ensure interventions were documented, whether actions were timely, and whether the participant, legal representative/legally responsible adult(s), and/or circle of support were satisfied with the outcome.

Assessment, Investigation and Follow-up of Event Occurrences

Assessment and investigation of all reported events will begin within two weeks of receipt of Event Occurrence Form—sooner if circumstances warrant it. The CCT project nurse and QA staff will take steps to protect the participant's health and welfare to prevent future incidents by reviewing medical services to ensure appropriate medical attention was sought, and review of coroner's reports, as needed. In addition, coordination with other agencies will take place to gather and review the results of their investigations and use their information to prevent the recurrence of similar problems.

Development of a Remediation Plan

The CCT project nurse and QA staff will solicit input from a participant (or surrogate decision-maker, provider, and the participant's primary care physician, if needed) to develop a plan of action. Waiver case managers/service coordinators will make adjustments to the comprehensive service plan to ensure that the participant continues to receive necessary services and supports. If the event occurred within 60 days of discharge, the transition coordinator will also be involved in the process.

Evaluation of steps taken to prevent recurrence of the situation

The results of the analysis are presented semi-annually, annually, or as needed by to the LTCD management and CCT project teams. Together, they will determine what changes in training, education, policies and/or procedures need to be made to protect the health and safety of demonstration participants. Evidence of the effectiveness of the changes will be discovered through the annual Case Record Review performed by QA Unit.

DHCS' QMS Process after the Demonstration Ends

As discussed, demonstration participants will be enrolled in the state's currently approved HCBS waivers for which they are eligible. Each of these systems has an approved quality oversight plan in place. Demonstration participants' plans of care will

be part of the quality and monitoring reviews pertinent to each system. Because they will be immediately enrolled in existing systems, there is no issue with transition from the demonstration to HCBS at the end of each participant's 12-month demonstration period. The following information is related to QMS once the demonstration ends after 12 months, or if the participant chooses to disenroll early.

The State's approved HCBS waivers have quality monitoring and oversight plans in place. These plans include:

- Delegated authority through an existing Interagency Agreement (DDS, CDA, DMH, and DSS) to administer and oversee service provision.
- Back-up emergency plans
- Incident reporting
- Risk assessment and remediation

As a baseline standard, a representative sample of participant service plans will be reviewed by the same state oversight unit which is responsible for the QA component of the NF/AH waiver. That component has been approved as Appendix H of the NF/AH HCBS waiver #0139.90.R3 approved for the period July 1, 2007 through June 30, 2012.

Additionally, lead organizations under the demonstration are required, through their agreement, to have plans in place to ensure transition plans include back-up services, incident reporting, and risk assessment and remediation.

HCBS QMS for 1915(c) Waivers

There are six QMS assurance areas to which the 1915(c) is held, as listed earlier in this section. These levels are: 1) LOC determined; 2) Service plan described; 3) Identification of qualified HCBS providers; 4) Health and Welfare; 5) Administrative Authority; and 6) Financial Accountability. All these topics together provide a checks and balance system to assure that demonstration participants receive safe and competent care to meet their health and welfare needs. Below is listed information on each specific waiver to which participants might be enrolled. Once the participant's time in the demonstration is completed, s/he will continue in the chosen waiver so long as s/he continues to meet clinical and Medi-Cal eligibility requirements. While they continue under the waivers, the following QMS systems will be in place.

Assisted Living Waiver Pilot Project (ALWPP)

DHCS is responsible for administration and oversight of the ALWPP. DHCS contracted with the NCB Corporation to design and implement the Quality Assurance and Improvement program which has been developed in accordance with specific waiver requirements and covers the following areas: quality of care; participant experience; care coordination; complaint monitoring and incident report monitoring; individual service plan; providers; assisted living bundled services; participant access; client-centered service; planning and delivery; provider capability and capacity; client safeguards; client outcomes and satisfaction; and system performance.

Developmental disability (DD) Waiver

The QMS model is built upon the premise that quality assurance is an essential component of the manner in which the work is accomplished. According to the renewal DD waiver application (Appendix H, p H-1), "It embodies the notion that discovery is a by-product of the work at hand and does not require participants in the system to generate special reports to satisfy the need to understand how the system is performing. Within this context, remediation and improvement will not only benefit the system, but will make the day-to-day work of the participants in the system more meaningful and effective." All levels of the system will be involved in QMS, to include the entire developmental disability service delivery system.

MSSP Waiver

The California Department of Aging (CDA) and DHCS monitor the quality control measures described in the waiver and MSSP Site Manual in order to ensure that the quality of services provided under the waiver and the state plan, to persons served under the waiver, are based on the monitoring activities of both departments pursuant to the CDA and DHCS Monitoring and Oversight Protocol(s).

Other Quality Topics Specified by CMS

Unique Demonstration Identifier

Demonstration participants will be assigned a unique identifier so that claims and records can be extracted from TARs and the existing Medi-Cal MMIS and paid claims files. Parallel manually kept records will augment the electronic files so that the state can supply demonstration participant data to:

- Report participant demographics
- Report utilization of QHCBS, demonstration and supplemental (if any) services
- Inform the CMS evaluation

Waiver Capacity

The state currently has capacity, as applicable, in each of its approved waivers. During the first operational year (CY 2008), demonstration participants will be enrolled, when feasible, into the Nursing Facility/Acute Hospital (NF/AH) waiver. Welfare and Institutions Code § 14132.99 provides the authority to reserve 250 waiver slots specifically for this purpose. The California Department of Aging has excess capacity in the MSSP waiver for appropriate demonstration participants. Although the Assisted Living Waiver Pilot Project has reached capacity, DHCS will ensure capacity is available when needed. Project staff are collaborating with waiver administrators from partnering departments to ensure capacity in the future.

HCBS Waiver Wait Lists

Demonstration participants' service needs will be accommodated immediately by one of the state's HCBS waivers or state plan programs. Participants will not be placed on HCBS wait lists; therefore, management of wait lists is not applicable to CCT.

Definition of Hard To Serve Children

CMS questioned which institution would be the transition point for obese children. If an obese child is to be considered as a potential demonstration participant, s/he must be residing in a nursing facility such as a pediatric subacute care facility. In addition, all other requirements for participation in the demonstration must be met.

Use of Managed Care and the Subsequent Reporting Requirements

While managed care programs may be appropriate for CCT participants, initially they will not be enrolled into County Organized Health Systems—Health Insuring Organizations of California 1915(b) waivers referenced in Appendix V, nor will they have the option of enrolling into the Program of All-Inclusive Care for the Elderly (PACE) until DHCS, programs and plans establish acceptable methodologies to capture expenditures and secure CMS' approval.

Supply of Trained Personal Care Service Providers

The supply of trained personal care services providers has grown over the past few years as the demand for their services has increased. With the expansion of the IHSS and IHSS Plus Services, more opportunity is provided for eligible, qualified individuals (including participants' family members and friends) to be hired, trained and serve as personal care workers.

The self-direction focus of IHSS Plus gives beneficiaries of IHSS the ability to hire people who might otherwise be giving care as a volunteer, thus contributing somewhat to an expansion of the workforce. Additionally, these personal attendants are receiving training which may become a billable skill of their own.